

### B. Remarks

The claims are 1-22, with claims 1 and 3 being in independent form.

Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following remarks.

Claims 1, 2, 8-11, 15-19, 21 and 22 stand rejected under 35 U.S.C. § 103 (a) for allegedly being obvious in view of Haraldsson et al., Journal of the American Oil Chemists Society, Vol. 74, No. 11 (1997), pages 1419-1424 (*Haraldsson I*), Journal of the American Oil Chemists Society, Vol. 74, No. 11 (1997), pages 1425-1429 (*Breivik*) and JFS Envirohealth Limited (GB 2350610 A) (*JFS*). Applicants respectfully traverse this rejection.

The present invention is directed to a lipase catalysed esterification of marine oils. More specifically, the claimed invention relates to a process for separating ethyl or methyl ester fraction enriched in EPA (eicosapentaenoic acid, C20:5) and a free fatty acid fraction enriched in DHA (docosahexaenoic acid, C22:6) from a mixture of such compounds that has been obtained by direct esterification of fish oil free fatty acids with ethanol or methanol using lipase, followed by molecular distillation.

In contrast to the present invention, *Haraldsson I* fails to disclose the direct esterification of fish oil free fatty acids. In addition, *Haraldsson I* also fails to disclose the separation of DHA in free fatty acid form from EPA in ester form. Hence, *Haraldsson I* fails to render the present claims obvious.

*Breivik* does not remedy the deficiencies of *Haraldsson I*. *Breivik* teaches the alcoholysis of fish oil triglycerides and takes advantage of separation between a glyceride fraction enriched in DHA and an ethyl ester fraction by molecular distillation. Thus, *Breivik* discloses the separation between the glycerides and ethyl ester, however, it fails to teach or suggest the surprising and patentable process in the present patent application, namely, the claimed separation of free fatty acids and ethyl esters by molecular distillation.

*JFS* does not remedy the deficiencies of *Haraldsson I* either. *JFS* discloses a process that takes advantage of the better separation between volatile ethyl esters and non-volatile esters of alkoxy-alcohols or polyhydric alcohols (polyethylene glycol). However, *JFS* does not disclose the separation by molecular distillation between free fatty acids and ethyl esters of the present invention.

In sum, the cited combination of *Haraldsson I*, *Breivik* and *JFS* fails to disclose the claimed invention. Therefore, Applicants respectfully request withdrawal of the §103 rejection.

Claims 3-7, 12-17 and 20-22 stand rejected under 35 U.S.C. § 103 (a) for allegedly being obvious in view of Journal of the American Oil Chemists Society, Vol. 74, No. 11 (1997), pages 1425-1429 (*Breivik*), *JFS Envirohealth Limited* (GB 2350610 A) (*JFS*) and Haraldsson et al., Journal of the American Oil Chemists Society, Vol. 74, No. 11 (1997), pages 1419-1424 (*Haraldsson I*). Applicants respectfully traverse this rejection.

The present invention describes the alcoholysis with a heavy alcohol (e.g. hexanol) followed by ethanolysis and subsequent separation by molecular distillation between a heavy alcohol ester fraction enriched in DHA and a light alcohol ester fraction. However, such a separation cannot be foreseen from the cited art which describe separation between much heavier alcohols (glycerol, alkoxy-alcohols or polyethylene glycol), a separation that is much easier to achieve compared to the process of the present invention. In addition, it cannot be obvious for someone skilled in the art on basis of the cited prior art, that the reaction mixture from the ethanolysis of free fatty acids is separable by molecular distillation. The process leading to a free fatty acid fraction with high content of DHA is therefore still surprising and patentable. Thus, the cited combination of *Breivik*, *JFS* and *Haraldsson I* fail to render the present invention obvious.

Accordingly, for all of the above-noted reasons, Applicants respectfully request withdrawal of the 103 rejections.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Raymond R. Mandra/  
Raymond R. Mandra  
Attorney for Applicants  
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3800  
Facsimile: (212) 218-2200

FCHS\_WS 2101428v1